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10/749,468

12/31/2003

Adam H. Molina

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LOS ANGELES, CA 90067

EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

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DELIVERY MODE

04/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |                                      |  |
|------------------------------|---|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/749,468    | <b>Applicant(s)</b><br>MOLINA ET AL. |  |
|                              | <b>Examiner</b><br>VICTORIA P. CAMPBELL | <b>Art Unit</b><br>3763              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/25/04, 1/7/05, 5/5/05</u> .                                 | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the second Office Action based on the 10/749468 application filed December 31, 2003. Claims 1-48 as amended are currently pending and considered below.

#### ***Election/Restrictions***

Applicant's election with traverse of Invention IV in the reply filed on October 6, 2006 is acknowledged. The traversal is on the ground(s) that Inventions IV and V are not restrictable because the method of Invention V could only make the product of Invention IV. The examiner agrees and hereby withdraws the previous restriction requirement. Accordingly, all claims as presented in the amendment filed May 5, 2007 are considered pending.

#### ***Drawings***

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings, notably figure 2, are informal in format and are replete with markings. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Specification***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 11, 20, and 31 recite the limitation "wherein the outer layer provides a barrier against diffusion of carbon dioxide". There is no mention of this limitation in the specification.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-11, 21-34, 38, 39, and 45 are rejected under 35 U.S.C. 102(a) as being anticipated by WIPO Publication WO 03/064909 A1 to Donohue et al.

Regarding claims 32-34, 45, and 1-11, Donohue et al teach a tubing comprising at least one layer of COPE (Paragraph [0016]) wherein the at least one layer of COPE, substantially free of other materials, is the outer layer (Fig. 1, #1).

Donohue et al also teach a tubing with no more than one layer of COPE material (Fig. 1) and a tubing with essentially no more than one layer of COPE material (Fig. 1). Donohue et al further teach a tubing with an inner layer (Fig. 1, #3) comprising a HDPE (Paragraph [0018]) or a polyurethane (Paragraph [0019]), and an intermediate layer (Fig. 1, #2) for bonding, comprised of EVA (Paragraph [0020]). Donohue et al also teach that the tubing is free of PVC (Paragraph

[0008]). Additionally, COPE is itself a barrier to carbon dioxide, so Donohue et al also teach a tubing with an outer layer providing a barrier against carbon dioxide (Fig. 1, #1).

Regarding claims 38, 39, and 21-31, Donohue et al teach a process of making a tubing wherein a COPE is selected and formed into a tube where the COPE is the outer layer (Paragraph [0021]) and the tubing has no more than one layer of the COPE material (Fig. 1, #1). Donohue et al further teach a process of forming a tubing with a COPE outer layer (Fig. 1, #1), a bonding intermediate layer (Fig. 1, #2) made of EVA (Paragraph [0020]), and an inner layer (Fig. 1, #3) made of HDPE (Paragraph [0018]) or polyurethane (Paragraph [0019]), wherein each of the layers is made by extruding (Paragraph [0021]). Donohue et al also teach co-extrusion of the layers (Paragraph [0021]) and that the tubing is free from PVC (Paragraph [0008]) and the outer layer is a barrier to carbon dioxide (Fig. 1, #1).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3763

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al in view of USPN 6,248,093 B1 to Moberg.

Donohue et al teach all of the limitations of claims 12-20 as described above regarding the same limitations disclosed in claims 32 and 1-11, but fail to teach or disclose the tubing is connected to a medical device wherein the device comprises a reservoir and a pump to deliver insulin through the tubing.

However, Moberg teaches a drug delivery system (Fig. 1) combining a pump (Fig. 1, #101, 102, 103, 104), reservoir (Fig. 1, #105), and tubing (Fig. 1, #106) for the delivery of insulin (Col. 1, lines 14-16).

Donohue et al and Moberg are analogous art because they are from the same field of endeavor/problem solving area of insulin delivery. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Donohue et al and Moberg before him or her to use the tubing of Donohue et al in the system of Moberg because Donohue et al disclose their tubing can be used in insulin delivery systems (Paragraph [0008]). Therefore, it would have been obvious to combine Donohue et al with Moberg to obtain the invention in the instant claims.

9. Claims 35-37 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al in view of USPN 6,406,767 B1 to Mueller.

Donohue et al disclose the tubing of claim 32 and the method of claim 38 as described above, but fail to disclose a tube with multiple layers of COPE material interspersed with adhesive. Mueller discloses a tubing wherein the intermediate layer is made of a COPE material (24) that can be co-extruded. This layer could replace the intermediate layer of Donohue et al or in addition to the EVA layer (2), thus creating a tubing with multiple COPE layers with intermediate adhesive.

Donohue et al and Mueller are analogous art because they are from the same field of endeavor/problem solving area of medical tubings. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Donohue et al and Mueller before him or her to modify the tubing of Donohue et al to

include the additional COPE layer of Mueller because it allows the manufacturer to adjust the flexibility of the tubing (Mueller Col. 3, line 39). Therefore, it would have been obvious to combine Donohue et al with Mueller to obtain the invention in the instant claims.

10. Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al.

Regarding claims 43 and 44, Donohue et al disclose both dual and tri layer tubing wherein COPE comprises the outer layer. It would therefore be obvious to one having ordinary skill in the art to extrude just the COPE into a tube in order to minimize material cost (especially that of expensive polyurethane, Donohue et al Paragraph [0004]) while still taking advantage of the properties of COPE.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell  
Examiner, AU 3763

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Supervisory Patent Examiner, Art Unit 3763